IPOMEANOL

NSC - 349438

Chemical Name: 1-(3-Furanyl)-4-hydroxy-1-pentanone

CAS Registry Number: 55659-41-1

Molecular Formula: $C_9H_{12}O_3$ M.W.: 168.2

How Supplied: Injection, 20 mg, vial: supplied as a clear, colorless liquid containing 10 mg/mL of ipomeanol in 0.9% sodium chloride, USP, and sodium hydroxide to adjust pH to 4 to 7, in a 3 mL flint vial.

Injection, 500 mg, vial: supplied as a clear, colorless liquid containing 10 mg/mL of ipomeanol in 0.9% sodium chloride, USP, and sodium hydroxide to adjust pH to 4 to 7, in a 60 mL flint vial.

Storage: Store the intact vials stored under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Three lots have maintained stability for 5 years under refrigeration (2-8 °C). The intact vials were unstable at elevated temperature (50 °C).

Aqueous solutions of ipomeanol are very stable over a pH range of 3 to 8.

Dilution of the ipomeanol to a concentration of 0.1 mg/mL in 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, in glass bottles and PVC plastic bags yielded the following results:

Percentage of Initial Ipomeanol^a Remaining in Solution

			Days		
Diluent	Temp (°C)	Container	1	2	3
D5W ^b	37	glass	100	100	100
		PVC	99	98	97
	25	glass	100	100	100
		PVC	99	99	98
	4	glass	100	100	100
		PVC	100	100	100
NS^c	37	glass	99	99	100
		PVC	99	97	95
	25	glass	99	100	100
		PVC	98	98	98
	4	glass	100	100	100
		PVC	99	99	100

⁽a) Initial ipomeanol concentration 0.1 mg/mL

⁽b) 5% Dextrose Injection, USP

⁽c) 0.9% Sodium Chloride Injection, USP

CAUTION: Ipomeanol is a potent lung toxin (1,2,3). (Refer to toxicology information in the clinical brochure.) Great care should be taken by those preparing and handling ipomeanol to avoid contact with the product or its dilutions, including avoiding the formation of aerosols during preparation. The use of a suitable biological safety cabinet and protective gloves, gowns, masks, eye protection, etc., is strongly recommended.

Route of Administration: Intravenous

References:

- 1. Wilson BJ, Yang DTC, and Boyd MR, Nature 227:521-522, 1970.
- 2. Boyd MR and Wilson BJ, J Agric Food Chem 20:428-430, 1972.
- 3. Elhawari M, et al: Proc AACR 28:440, 1987.